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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,920	03/26/2004	Ruediger Stendel	1194-280	6751

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
01/28/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/809,920	STENDEL ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *7-19 and 21-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,20,24 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *all*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-6, 20, 24 and 25) in the reply filed on 11/13/07 is acknowledged.

Claims 7-19, and 21-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/13/07.

Specification

The disclosure is objected to because of the typographical error in page 9, third to last line of paragraph 0040, the word "superatants" should read "supernatants".

Claim Objections

Claim 24 is objected to because of the typographical error in line 3, the word "adminstrable" should read "administrable".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are rejected in the use of the limitation "a system for preventing or inhibiting growth of cancer cells". The present specification does not define the term "system", therefore, it is not clear what exactly is "a system". Is it an apparatus, a machine, or indeed a method? It is noted that applicant did not elect the method claims for examination. Accordingly, for examination purpose, the claims are interpreted as composition claims.

Further, the claims are rejected because the phrase "in combination with an intravenously administrable MTA for intravenous administration" is confusing. What is "an intravenously administrable MTA for intravenous administration"? The specification does not provide any definition for such limitation. Moreover, the specification does not appear to provide any formulation suitable for intravenous administration. Claim 24 depends in claim 1, which has already recited the limitations "MTA" and "combination with a biodegradable adhesive capable of adhering to tissue of a living subject".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 20, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calabresi et al. WO 01/39763 A2, in view of Filler et al. US 6,919,067.

Calabresi teaches a method of inhibiting tumor growth in a mammal by administering to the mammal a composition comprising taurolidine, taurultam, or a biologically active derivative thereof (abstract; and page 1, lines 10-28). The composition is administered intravenously, topically, or infused (ID).

Calabresi does not expressly teach the composition comprising claimed bioadhesive.

Filler teaches a composition comprising a radiotherapeutic agent or agent that can be converted to a radiotherapeutic, and a tissue glue (abstract). Filler further teaches the use of tissue glue as a matrix suitable for topical or other application to the locus of treatment (column 3, lines 28-50). Tissue glue includes fibrin sealant matrix (column 9, lines 23-60). Thus, it would have been obvious to one of ordinary skill in the art to modify the composition of Calabresi using fibrin tissue glue matrix as a drug-loaded matrix to obtain the claimed invention, because Filler teaches the use of fibrin glue matrix to provide controlled/delayed/slow release of therapeutic agent (column 9, lines 38-40; lines 66 through column 10, lines 1-30); because Filler teaches the use of fibrin glue matrix as a carrier for intravenous and topical formulations for the treatment of brains cancer (column 13, lines 54 through column 14, lines 1-54), and because Calabresi teaches the desirability of preparing compositions comprising slow release matrix (page 13, lines 21 through page 14, lines 1-6).

Regarding claims 2-6, Calabresi does not explicitly teach the concentration of the composition. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to, by routine experimentation determine a suitable concentration that would fall within the claimed concentration. This is because Calabresi teaches the same method of administration suitable for the same treatment using the same therapeutic agent. This is further because Fill teaches the use of fibrin glue is known in radiotherapeutic art to control/slow/delay the release of the therapeutic agent.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
Primary Examiner
Art Unit 1615